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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/670,128	09/26/2000	E. Premkumar Reddy	6056-251-CT1	5662

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EXAMINER

NICKOL, GARY B

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 11/13/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/670,128

Applicant(s)

REDDY ET AL.

Examiner

Gary B. Nickol Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 September 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11-13, 15 and 16 is/are pending in the application.
- 4a) Of the above claim(s) 11 and 12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13, 15 and 16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- ☐ Interview Summary (PTO-413) Paper No(s). _____
- ☐ Notice of Informal Patent Application (PTO-152).
- ☐ Other: _____

Request for Continued Examination

The request filed on 09-05-03 for a Continued Examination (RCE) under 37 CFR 1.114 based on parent Application No. 09/670128 is acceptable and a RCE has been established. An action on the RCE follows.

Claims 11-13, and 15-16 are pending.

Claims 11-12 have been withdrawn from further consideration by the examiner under 37 CFR 1.142(b) as being drawn to non-elected inventions.

Claims 13, 15-16 are currently under consideration.

Rejection Maintained:

Claims 13, 15-16 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Garcia *et al.* (Cell Growth & Differentiation, Vol.8, pages 1267-1276, December 1997, IDS) and Takemoto *et al.* (Proc.Natl.Acad.Sci., Vol. 94, December 1997, pages 13897-13902) as further evidenced by (Univ. Mich Med. School, Proc. Ann. Meet. Assoc. Cancer Res., 1997, 38, A3725, meeting abstract) for the reasons of record.

Applicants reiterate (Paper No. 19, page 8) that Garcia does not correlate the activation of STAT-3 with the ability of the cells to metastasize, but rather characterizes STAT-3 protein activation as an early event in src-induced oncogenic transformation. This argument has been considered but is not found persuasive for the reasons of record.

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Applicants further point out that tumorigenesis and metastasis could be under separate genetic controls, and that the molecular mechanisms responsible for transformation of normal cells were not necessarily the same as those responsible for metastasis. This argument has been considered but is not found persuasive. Even if the mechanisms between the formation of a tumor and its ability to metastasize are under different genetic controls, the verification of such does not take away from the teachings of the prior art considered as a whole. Applicants are reminded that preamble statements (such as those presented herein, i.e. “determining the metastatic potential”) must be read in the context of the entire claim. The determination of whether preamble recitations are structural limitations or mere statements of purpose or use “can be resolved only on review of the entirety of the [record] to gain an understanding of what the inventors actually invented and intended to encompass by the claim.” *Corning Glass Works*, 868 F.2d at 1257, 9 USPQ2d at 1966. If the body of a claim fully and intrinsically sets forth all of the limitations of the claimed invention, and the preamble merely states, for example, the purpose or intended use of the invention, rather than any *distinct definition* of any of the claimed invention’s limitations, then the preamble is not considered a limitation and is of no significance to claim construction. *Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1305, 51 USPQ2d 1161, 1165 (Fed. Cir. 1999). See also *Rowe v. Dror*, 112 F.3d 473, 478, 42 USPQ2d 1550, 1553 (Fed. Cir. 1997). See **MPEP 211.02**

In this case, it is the *steps* of the claimed method that set forth the limitations of the claimed method not the preamble because there is no distinct definition of “metastatic potential”. As noted above, it is the specification which teaches what the inventors intended to

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encompass by the claims, and in this case the specification teaches (page 13, lines 13+) that prognosis or grade of malignancy is determined by the difference in the amount of antibody bound by the normal and test samples. A low or zero level of antibody binding is indicative of a lower grade of malignancy and a more favorable patient prognosis. Antibody binding levels above that reflected in a normal control sample is indicative of a higher grade of malignancy, and a less favorable patient prognosis. Hence, Garcia anticipates determining the level of activated STAT-3 protein in tumor tissues versus their normal tissue counterparts by contacting the samples with an antibody which binds the phosphorylated protein.

Applicants further argue that the teachings of Takemoto only discuss STAT-3 protein activation in terms of cellular transformation and JAK mediation of STAT-3 activation. Applicants further argue that the teachings of the Univ. of Michigan abstract discloses that STAT-3 protein is not detectable in EGF negative human breast cancer cells and that the abstract is silent on the type of kinases that would activate STAT-3 protein in metastatic tumors. These arguments have been carefully considered but are not found persuasive. Applicant has argued and discussed the references individually without clearly addressing the combined teachings. It must be remembered that the references are relied upon in combination and are not meant to be considered separately as in a vacuum. It is the combination of all of the cited and relied upon references which made up the state of the art with regard to the claimed invention. Applicant's claimed invention fails to patentably distinguish over the state of the art represented by the cited references taken in combination. In re Young, 403 F.2d 754, 159 USPQ 725 (CCPA 1968); In re Keller 642 F.2d 413, 208 USPQ 871 (CCPA 1981). Furthermore, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of

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the primary reference and it is not that the claimed invention must be expressly suggested in any one or all of the references; but rather the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. In re Keller, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). Thus, applicant's arguments have not been found persuasive and the rejection is maintained.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary B. Nickol Ph.D. whose telephone number is 703-305-7143. The examiner can normally be reached on M-F, 8:30-5:00 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Gary B. Nickol, Ph.D.
Examiner
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GBN

November 12, 2003

Hayden Michael